JPEO-CBD

CBMS
CHEMICAL BIOLOGICAL MEDICAL SYSTEMS

# JPM Chemical Biological Medical Systems
# Advanced Planning Brief to Industry

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# Outline

- Program Overview
- Warfigther needs
- Acquisition Strategy
- Technical Challenges
- Upcoming Business Opportunities
- Contacts

# Overview

- **Develop, Procure, Field, and Sustain Premier *Medical Protection and Treatment Capabilities* Against Chemical and Biological Warfare Agents.**

- **Ultimate Outcomes Are FDA Licensed Drugs, Medical Devices and Vaccines**

# Warfighter Needs

- **Provide Medical Protection Against Nerve Agent-induced Seizures and Subsequent Neurologic Damage**
  - **Advanced Anti-convulsant System (AAS) Will Replace Convulsant Antidote Nerve Agent (CANA) System**
  - **Intramuscular Auto-Injection of Drug (Midazolam) for Enhanced Control of Seizures**
  - **Effective Against Broader Spectrum of Nerve Agents and Non-traditional Agents (NTAs)**

# Warfighter Needs (cont)

- **Provide Medical Protection Against a Broader Spectrum of Traditional As Well As Non-traditional Nerve Agents**
  - **Improved Nerve Agent Treatment System (INATS) Active Ingredient Will Replace and Provide Better Protection Than Current Oxime, 2-PAM**
  - **System Approach Will Also Develop Broader Indications for Pretreatment Pyridostigmine Bromide**
  - **INATS Will Use Current Delivery System**

# Warfighter Needs (cont)

- **Provide Rapid, Portable Medical Diagnostic Capability for Biological Warfare Agents (BWAs) And Pathogens of Operational Concern**
  - **Joint Biological Agent Identification and Treatment System (JBAIDS) Will Provide Portable Diagnostic Capability to War Fighter.**
  - **COTS System Capable of Identifying 10 BWAs**
  - **Evolutionary Approach: Detection to Diagnostics; Expand BWA Capability; Reduce to Hand Held Device; Reporting System Interoperability**

# Warfighter Needs (cont)

- **Provide Medical Prophylaxes for Protection Against Biological Warfare Agents**
  - **Prime Systems Contract Integrator: Dynport Vaccine Company (DVC) Uses Commercial Biotech to Meet DoD Vaccine Requirements**
  - **DVC Obtains and Maintains FDA Licenses**
  - **Special Studies Allows DVC To Evaluate and Integrate Emerging Technologies Into Vaccine Systems**

# Acquisition Strategy

- **Outcomes Are FDA Licensed Products**
- **Looking for Industry off the Shelf Solutions**
- **Leveraging International and Other Government Agency Efforts**
- **Seeking More Funding to Support More Products**

# Technical Challenges

- **Proving Product Efficacy**
  - **FDA Animal Rule Rule Allows Use of Animal Instead of Human Trials to Prove Product Efficacy**
  - **Animal Rule Approach Not Necessarily Cheaper or Faster**

- **Facilities**
  - **Capable of Animal Testing for Biological and Chemical Warfare Agent Countermeasures**

- **Manufacturing**
  - **FDA Process Is Averse to Technology Insertion**
  - **Complexity of Biological Manufacturing Process**

# Technical Challenges (cont)

**AAS**

- **Proving Efficacy Using FDA Directed Combination of Animal Rule and Human Testing (Epileptic Seizures Comparable to Nerve Agent Seizures)**

**INATS**

- **Active Ingredient Has Not Previously Been in Humans**

**JBAIDS**

- **FDA Approval of Device and Multiple Assays**
- **Miniaturization & Interoperability**

# Upcoming Business Opportunities

**AAS:**

- **RFP for System Integrator** — **FY04**

**INATS**

- **RFP for System Integrator** — **FY06**

**JBAIDS**

- **RFP for Miniaturization (unfunded)** — **FY08**

**JVAP**

- **Subcontracts through DVC**

# Points of Contact

- **PM Medical Identification & Treatment Systems**
  - **LTC Edward Clayson 301-619-8425**
    **edward.clayson@us.army.mil**

- **PM Joint Vaccine Acquisition Program**
  - **LTC Travis Bernritter, 301-619-7083**
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- **DVC**
  - **Business Development Director:**
    - **Barbara Solow, 301-607-5241**
  - **Contracts:**
    - **Donna Dawson, 301-607-5009**
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